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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant : Takaaki SATO et al.

Serial No. : 09/661,305

Group Art Unit : 1645

Filed : September 13, 2000

Examiner : Natalie Davis

For : NADE BINDING PROTEINS

ELECTION WITH TRAVERSE

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This is in response to the Requirement for Restriction mailed August 3, 2001.

Inasmuch as the Requirement sets a one-month shortened statutory period for response which expires on September 3, 2001, and September 3, 2001 being a Federal Holiday (Labor Day), this response, in accordance with 37 C.F.R. § 1.7.

REMARKS

Claims 1-6 are pending in the application.

Restriction Requirement

The Examiner has required restriction to one of the following inventions under 35 U.S.C.

121:

I. Claims 1-2 drawn to a screening agent for a medicament of an apoptosis associated

disease which can bind a protein, and is classified in class 435, subclass 7.1.

II. Claims 1-2 drawn to a screening agent for a medicament of an apoptosis associated disease which can bind DNA, and is classified in class 436, subclass 94.

III. Claims 3-5 drawn to a method for screening a medicament, classified in class 435, subclass 4.

IV. Claim 6 drawn to a medicament for treatment, prevention and/or diagnosis of an apoptosis associated disease, classified in class 424, subclass 9.1.

In an attempt to justify the requirement for restriction, the Examiner has taken the position that the inventions are distinct, each from the other, because the inventions of Groups I and III are related as product and process of use and the products of Groups I, II, and IV may be used for a number of different processes that are very much unrelated. Further, the Examiner states that the products of Groups I, II, and IV are drawn to structurally and functionally different molecules which require different reagents and steps to make and characterize them.

Election

In order to be responsive to the Requirement for restriction, Applicants elect the invention set forth in Group III (claims 3-5), with traverse.

Initially, in regard to the Requirement with respect to Groups I and II, Applicants respectfully submit the following. The inventions of Groups I and II are related such that Election of Species analyses are appropriate. In this regard, the Examiner is reminded that for an election Requirement

to be proper the species must be mutually exclusive. M.P.E.P. §806.04(f). In this case, it is respectfully submitted that this asserted species of Group I (claims 1-2) are not mutually exclusive with respect to the asserted species of Group II (claims 1-2). Initially, while not wanting to restrict the scope of the claims, Applicants note that the claimed screening agent will bind to either a protein, or its DNA sequence. Since a protein is encoded by a DNA sequence, and treatment or prevention and/or diagnosis may be accomplished through activity on either, these asserted species are not mutually exclusive. In view of the above, the Election should be withdrawn.

Furthermore, the Requirement should be withdrawn because there is no serious search burden. In MPEP Chapter 800, the Office sets forth its policy by which examiners are guided in requiring restriction under 35 U.S.C. §121. Section 803 states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions."

Although Groups I and II differ in that Group I is directed to a protein and Group II is directed to a DNA sequence, the underlying concepts are quite similar. Thus, a search for the DNA sequence of Group II should cover areas relevant to the protein of Group I. In other words, for examination purposes, if a search area were relevant to the DNA of Group II, it would also be relevant to the protein of Group I. The Examiner is reminded that a protein can be defined by its amino acid sequence or its DNA sequence. Conversely, if a search area were relevant to Group I, it would be relevant to Group II. Therefore, as a practical matter, the searches for the Groups should

significantly overlap. Thus, the search burden would not be serious.

Further, Group III differs from Group I and II in that Group III is directed to a method of using the medicaments of Group I and II to screen for a medicament. Here again, the underlying concepts of the Groups are quite similar. Thus, a search for the screening agent of Groups I and II should cover areas relevant to the method of its use of Group III. In other words, for examination purposes, if a search area were relevant screening agent of Groups I and II, it would also be relevant to the method of its use of Group III. Conversely, if a search area were relevant to Group III, it would be relevant to Groups I and II. Therefore, as a practical matter, the searches for the Groups should significantly overlap. Thus, the search burden would not be serious.

In this regard, the searches for the Species should significantly overlap, and the search burden would not be serious.

Furthermore, as the Examiner appreciates, in order to justify a requirement for restriction the difference between the invention defined by the various groups of the claims must be material. Despite this requirement, although the Examiner has characterized the noted difference as being material, the Examiner has not stated or offered a definition of what is "materially different" to justify a requirement for restriction, or offered an explanation as to why the mentioned differences are material for restriction requirement purposes.

Absent an explanation of this concept, it is respectfully submitted that the Examiner has not explained how such a difference is sufficiently "materially different" so as to justify the Restriction

and Election between the Species. With regard to the Restriction, the Examiner has merely stated that Groups I, II and IV are drawn to structurally and functionally different molecules with different immunological properties, and that each invention requires different reagents and steps to make and characterize it.

It is also important for the Examiner to understand that Applicants have paid a filing fee for an examination of all the claims in this application. If, however, the Examiner refuses to examine all the claims paid for when filing this application and persists in requiring Applicants to file divisional applications for each group of claims, the Examiner is essentially forcing Applicants to pay duplicative fees for the non-elected or withdrawn claims.

As a final note, even if the restriction requirement is maintained, if product claims are found to be patentable, withdrawn process claims which include the recitations of the product claims should be rejoined. The Examiner is reminded that M.P.E.P. §821.04 states:

However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of an allowable product claim will be rejoined.

Thus, if product claims are found to be allowable, the process claims of Group III which include the composition recitations of the allowed claims should be rejoined.

Therefore, Applicants respectfully request that the Restriction and Election requirement be reconsidered and withdrawn, in view of the unity of invention rules, the lack of a serious burden, and the lack of material differences between the Groups. Applicants also request that even if the

restriction requirement is initially maintained, if the product claims are found to be allowable, the process claims which have the recitations of the allowed product claims should be rejoined.

Still further, Applicants remind the Examiner that if a generic claim is found to be allowable, the claims of the nonelected species should be examined if they depend from or otherwise include each of the limitations of the allowed generic claim. See M.P.E.P. §809.02(c). Therefore, in the present case, if a generic claim is found to be allowable, Applicants submit that its dependent claims should be considered.

If the Examiner has any questions concerning this matter or the application, the undersigned can be contacted at the below-listed telephone number.

Respectfully submitted,
Takaaki SATO et al.


Stephen M. Roylance Reg. No.
Reg. No. 31,296 31,296

August 31, 2001
GREENBLUM & BERNSTEIN, P.L.C.
1941 Roland Clarke Place
Reston, VA 20191
(703) 716-1191